



General

Guideline Title

Antiphospholipid syndrome.

Bibliographic Source(s)

American College of Obstetricians and Gynecologists (ACOG). Antiphospholipid syndrome. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2011 Jan. 8 p. (ACOG practice bulletin; no. 118). [64 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American College of Obstetricians and Gynecologists (ACOG). Antiphospholipid syndrome. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 2005 Nov. 9 p. (ACOG practice bulletin; no. 68). [68 references]

Recommendations

Major Recommendations

The grades of evidence (I-III) and levels of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

The following recommendations are based on limited or inconsistent scientific evidence (Level B):

- Obstetric indications for antiphospholipid antibody testing should be limited to a history of one fetal loss or three or more recurrent embryonic or fetal losses.
- Testing for antiphospholipid antibodies should be performed in women with a prior unexplained venous thromboembolism, a new venous thromboembolism during pregnancy, or in those with a history of venous thromboembolism but not tested previously.
- In women with antiphospholipid syndrome (APS) and a history of stillbirth or recurrent fetal loss but no prior thrombotic history, prophylactic doses of heparin and low-dose aspirin during pregnancy and 6 weeks of postpartum should be considered.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- For women with APS who have had a thrombotic event, most experts recommend prophylactic anticoagulation with heparin throughout pregnancy and 6 weeks postpartum.
- For women with APS who have not had a thrombotic event, expert consensus suggests that clinical surveillance or prophylactic heparin use antepartum in addition to 6 weeks of postpartum anticoagulation may be warranted.
- For long-term management postpartum, patients with APS should be referred to a physician with expertise in treatment of the syndrome,

such as an internist, hematologist, or rheumatologist.

- Women with APS should not use estrogen-containing contraceptives.

Definitions:

Grades of Evidence

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Levels of Recommendation

Level A – Recommendations are based on good and consistent scientific evidence.

Level B – Recommendations are based on limited or inconsistent scientific evidence.

Level C – Recommendations are based primarily on consensus and expert opinion.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Antiphospholipid syndrome during pregnancy and postpartum

Guideline Category

Diagnosis

Management

Screening

Treatment

Clinical Specialty

Allergy and Immunology

Hematology

Internal Medicine

Obstetrics and Gynecology

Rheumatology

Intended Users

Physicians

Guideline Objective(s)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To provide evidence based recommendations for diagnosis and treatment of antiphospholipid syndrome

Target Population

Women with antiphospholipid syndrome during pregnancy and postpartum

Interventions and Practices Considered

Screening/Diagnosis

1. Lupus anticoagulant test
2. Anticardiolipin antibody of immunoglobulin G (IgG) and/or immunoglobulin M (IgM) isotype in serum or plasma
3. Anti- β_2 -glycoprotein I of IgG and/or IgM isotype in serum or plasma

Management

Pregnant Women

1. Serial ultrasonographic assessment
2. Antepartum testing in the third trimester

Long-term Management

1. Estrogen-free contraception
2. Referral to a physician with expertise in treatment of the syndrome

Treatment

Pregnant Women

1. Prophylactic low-dose aspirin and heparin
2. Postpartum anticoagulation
3. Corticosteroids
4. Intravenous immunoglobulin (IVIG) (considered but not recommended)

Major Outcomes Considered

- Fetal morbidity and mortality
- Maternal morbidity
- Incidence of vascular thrombosis and stroke
- Efficacy of treatment

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

The MEDLINE database, the Cochrane Library, and the American College of Obstetricians and Gynecologists' own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985–November 2009. The search was restricted to articles published in the English language. Priority was given to articles reporting results of original research, although review articles and commentaries also were consulted. Abstracts of research presented at symposia and scientific conferences were not considered adequate for inclusion in this document. Guidelines published by organizations or institutions such as the National Institutes of Health and the American College of Obstetricians and Gynecologists were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force:

I: Evidence obtained from at least one properly designed randomized controlled trial.

II-1: Evidence obtained from well-designed controlled trials without randomization.

II-2: Evidence obtained from well-designed cohort or case–control analytic studies, preferably from more than one center or research group.

II-3: Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence.

III: Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician–gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Level C recommendations.

Rating Scheme for the Strength of the Recommendations

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Level A – Recommendations are based on good and consistent scientific evidence.

Level B – Recommendations are based on limited or inconsistent scientific evidence.

Level C – Recommendations are based primarily on consensus and expert opinion.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate diagnosis and management of antiphospholipid syndrome during pregnancy and postpartum
- Improved maternal and fetal-neonatal outcome

Potential Harms

Not stated

Qualifying Statements

Qualifying Statements

The information is designed to aid practitioners in making decisions about appropriate obstetric and gynecologic care. These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2005 Nov (revised 2011 Jan)

Guideline Developer(s)

American College of Obstetricians and Gynecologists - Medical Specialty Society

Source(s) of Funding

American College of Obstetricians and Gynecologists (ACOG)

Guideline Committee

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

Composition of Group That Authored the Guideline

American College of Obstetricians and Gynecologists (ACOG) committees are created or abolished and their overall function defined by the Executive Board. Appointments are made for one year, with the understanding that such appointment may be continued for a total of three years. The majority of committee members are Fellows, but Junior Fellows also are eligible for appointment. Some committees may have representatives from other organizations when this is particularly appropriate to committee activities. The president elect appoints committee members annually.

Financial Disclosures/Conflicts of Interest

Not stated

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Guideline Availability

Electronic copies: None available

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 933104, Atlanta, GA 31193-3104; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the [ACOG Web site](#) .

Availability of Companion Documents

A proposed performance measure is included in the original guideline document.

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on October 8, 2007. The information was verified by the guideline developer on December

3, 2007. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection. This summary was updated by ECRI Institute on July 27, 2010 following the FDA drug safety communication on Heparin. This summary was updated by ECRI Institute on March 23, 2011. This summary was updated by ECRI Institute on March 10, 2014 following the U.S. Food and Drug Administration advisory on Low Molecular Weight Heparins.

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